COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13-X-2004
C(2004)4056

NOT FOR PUBLICATION

COMMISSION DECISION

of 13-X-2004

granting the marketing authorization for the orphan medicinal product for human use "Wilzin - Zinc acetate dihydrate" under Council Regulation (EEC) No 2309/93

(Text with EEA relevance)

ONLY THE FRENCH TEXT IS AUTHENTIC

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2], and in particular Article 10(2) thereof,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[3],

Having regard to the application submitted by Orphan Europe SARL on 24 March 2003 under Article 4(1) of Regulation (EEC) No 2309/93,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Human Use on 23 June 2004,

Whereas:

(1) Commission Decision C(2001)2052 of 31 July 2001 designated "Zinc acetate dihydrate" as an orphan medicinal product.

(2) The orphan medicinal product "Wilzin - Zinc acetate dihydrate" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4] as amended by Directive 2002/98/EC[5] and by Directive 2003/63/EC[6].

(3) It is therefore appropriate to authorise its placing on the market.

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[1] OJ L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 18, 22.1.2000, p. 1.
[4] OJ L 311, 28.11.2001, p. 67.
[5] OJ L 33, 8.2.2003, p. 30.
[6] OJ L 159, 27.6.2003, p. 46.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted for the orphan medicinal product "Wilzin - Zinc acetate dihydrate", whose characteristics are summarised in Annex I hereto. This orphan medicinal product is registered in the Community register of medicinal products under Nos:

EU/1/04/286/001 Wilzin-25 mg-Hard capsule-Oral use-Bottle (HDPE)-250 capsules

EU/1/04/286/002 Wilzin-50 mg-Hard capsule-Oral use-Bottle (HDPE)-250 capsules

Article 2

The marketing authorization concerning the medicinal product referred to in Article 1 shall be subject to compliance with all the conditions, particularly those relating to manufacture and importation, control and issue referred to in Annex II.

Article 3

The labelling and package leaflet concerning the orphan medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to Orphan Europe SARL, Immeuble “Le Guillaumet”F-92046 Paris-La-Défense - France.

Done at Brussels, 13-X-2004

For the Commission
Olli REHN
Member of the Commission